

### **REMARKS**

Applicants respectfully request reconsideration of the present Application. Claims 1, 12, and 23 have been amended and claims 29-34 are canceled herein. Claim 35 is newly submitted for consideration. Care has been exercised to introduce no new matter. Claims 1-4, 6-15, 17-25, and 35 are pending and are in condition for allowance.

#### **Rejections under 35 U.S.C. § 101**

Claims 12-15, 17-22 were rejected under 35 U.S.C. § 101 because the claimed invention is ostensibly directed to non-statutory subject matter. Applicants have amended independent claim 12 to recite computer-readable media comprising tangible media. As such, Applicants submit that independent claim 12 recites statutory subject matter. And claims 13-15 and 17-22 depend directly or indirectly from amended independent claim 12 and, therefore, also recite statutory subject matter. Applicants request withdrawal of the 35 U.S.C. § 101 rejection of claims 12-15 and 17-22 and allowance of the claims.

#### **Rejections under 35 U.S.C. § 112 First Paragraph**

Claims 29-34 were rejected under 35 U.S.C. § 112, first paragraph, as ostensibly failing to comply with the written description requirement. Claims 29-34 have been canceled herein. Applicants submit that the rejection thereof is now moot.

#### **Rejections under 35 U.S.C. § 112 Second Paragraph**

Claims 12-15 and 17-22 were rejected under 35 U.S.C. § 112, second paragraph, as ostensibly being indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention. Applicants have amended independent claim 12 to remove the feature indicated as unclear by the Office Action. Accordingly, Applicants

respectfully submit that independent claim 12 is not indefinite and particularly points out and distinctly claims the subject matter which the Applicants regard as the invention. Claims 14-15 and 17-22 depend directly or indirectly from amended independent claim 12. Accordingly, Applicants submit that these claims are also not indefinite and particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants request withdrawal of the 35 U.S.C. § 112 rejection of claims 12-15 and 17-22 and allowance of the claims.

**Rejections under 35 U.S.C. § 103 over Rosenfeld in view of Shen**

Claims 1-15, 17-22 and 29-34 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Rosenfeld, et al., U.S. Patent No. 6,804,656 (hereinafter “Rosenfeld”) in view of Shen, Pre-Grant U.S. Publication No. 2003/0212580 (hereinafter “Shen”). Applicants submit that claims 29-34 have been canceled herein and thus, the rejections thereof are moot.

**Independent Claim 1**

Independent claim 1, as currently amended, recites a system for analyzing clinically related data. Independent claim 1 has been amended herein to further recite that the inference engine compares result data from a control group that adheres to an altered guideline and from a non-control group that does not adhere to the altered guideline. *See Applicant's Specification* at ¶ [0024]. The result data includes clinical and cost data for patients treated by the control group and a non-control group. *Id.* The inference engine also reassesses the opportunity for improvement resulting from implementation of the altered guideline based on the comparison of the result data. *Id.*

In contrast, Rosenfeld describes providing continuous, expert network critical care services from remote locations. In Rosenfeld, a command center is provided at a remote

location at which a doctor is located. *Rosenfeld* col. 4, lines 53-57. A group of intensive care units (ICU) at disparate locations are provided with cameras and monitoring equipment such that patient data and communications are established between the command center and each of the ICUs. *Id.* at col. 4, lines 57-65. Clinical data is transmitted to the command center to allow the doctor to monitor and manage multiple patients at disparate ICUs from a single location. *Id.* at col. 5, lines 10-13. The clinical information is also submitted to a relational database that includes standardized guidelines for patient care, algorithms to support the intensive care regimen, order writing software, and knowledge-based algorithms that key the doctor to engage in preventative actions based on a patient's clinical information. *Id.* at col. 5, lines 13-24. Thus, a single doctor is able to manage multiple patients at various locations by being provided with the clinical information at a single location and is assisted in identifying issues by algorithms that analyze the clinical data transmitted from the patients' ICUs. *Id.* at col. 13, lines 36-43.

As such, *Rosenfeld* does not teach or suggest all of the features of Applicants' amended independent claim 1. *Rosenfeld* does not describe an inference engine comparing result data from a control group and a non-control group as recited by amended independent claim 1. *Rosenfeld* also fails to describe reassessing the opportunity for improvement resulting from implementation of the altered guideline based on the comparison of the control and non-control group. Although *Rosenfeld* discusses analyzing clinical data from patients, there is no discussion of comparing data from a control group and a non-control group or reassessing an opportunity for improvement based on such a comparison.

The Office Action cites *Shen* in support of the deficiencies of *Rosenfeld*, however Applicants respectfully submit that *Shen* fails to cure these deficiencies of *Rosenfeld*. *Shen*

describes management of information flow and workflow in medical imaging services. *Shen* ¶ [0037]. By *Shen*, various data items are collected throughout a patient's course of treatment by a medical imaging facility. *See id. generally*. A performance metrics module manipulates the data to calculate various flow metrics related to workflow and information flow to provide objective statistics that are useable to analyze the interaction of the workflow process with the information flow process. *Id.* at ¶ [0045]. An analysis tools module is also provided to perform practical and business performance analysis of the overall processes. *Id.* at ¶ [0046]. Using these modules, outcome metrics for performance measurements are generated such that diagnostic, clinical, service, and financial outcomes for the medical imaging facility can be quantified and analyzed. *Id.* at ¶¶ [0071]-[0076]. Further, risk assessment and utilization assessments of testing procedures can also be quantified. *Id.* at ¶¶ [0059] and [0102].

*Shen* also describes that organizational benchmarks and goals may be changed such that the changed goals and the effects thereof may be compared to the collected data. *Id.* at ¶ [0109]. Organizational process analysis is also described as allowing simulation and prediction of modified process outcomes with the new organizational goals. *Id.* at ¶ [0133].

Applicants are unable to find teachings provided by *Shen* that describe comparing result data from a control group and a non-control group or reassessing the opportunity for improvement resulting from implementation of the based on the comparison. Although *Shen* describes analysis metrics for use in identifying under-utilization and over-utilization of particular analytical imaging tests, among other analysis metrics, such analysis metrics are *not* the same as comparing result data from the control group and non-control group, as recited by amended independent claim 1. *See Shen* at ¶ [0014]-[0023]. The analysis metrics described by

Shen indicate usage of imaging tests. They do not compare data that results from adherence or non-adherence to an altered guideline.

Independent Claim 12

Independent Claim 12, as currently amended, recites tangible computer-readable media having computer-executable instructions embodied thereon, that when executed, perform a method of analyzing clinically related data. Independent claim 12 has been amended herein to more clearly recite accessing clinically related data that has been processed to generate multidimensional extensions of the raw data. The multidimensional extensions reflect groupings and logical structures not present in the raw data. *See Applicant's Specification* at ¶ [0017] and *see* U.S. Provisional Patent Application Serial No. 60/498, 283, incorporated by reference. Also independent claim 12 further indicates that selectively performing a comparative analysis of a first key performance indicator against the knowledge base uses the groupings and logical structures reflected by the multidimensional extensions of the clinically related data. *Id.*

Rosenfeld and Shen do not teach or suggest data that has been processed to generate multidimensional extensions of the raw data as recited by amended independent claim 12. Multidimensional data includes raw data that is enhanced to extend the data into logical structures reflecting meaningful groupings of the data not present in the raw data. *See U.S. Provisional Patent Application No. 60/498,283* at ¶ [0005]. Although Rosenfeld and Shen both discuss various forms of data, they do not describe processing such data to provide multidimensional extensions thereof.

Independent claim 12 has also been amended to further recite features similar to those described above for independent claim 1, such as, determining a control group of users that adhere to an altered guideline or policy, determining a non-control group of users that do not

adhere to the altered guideline or policy, and comparing subsequent data from the control group with subsequent data from the non-control group to identify a trend associated with implementation of the altered guideline or policy. *See Applicant's Specification* at ¶ [0024]. The comparative analysis is also updated using the trend to project an updated facility-wide outcome. *Id.* Accordingly, the remarks provided above for amended independent claim 1 apply equally to amended independent claim 12.

Applicants respectfully submit that Rosenfeld and Shen fail to teach or suggest all of the claim features of amended independent claims 1 and 12. Applicants submit that amended independent claims 1 and 12 are patentable over Rosenfeld in view of Shen. Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of amended independent claims 1 and 12. Amended independent claims 1 and 12 are believed to be in condition for allowance and such favorable action is hereby respectfully requested.

Claims 2-11, 13-15, and 17-22 depend directly or indirectly from amended independent claims 1 and 12. Applicants thus respectfully submit that Rosenfeld and Shen fail to teach or suggest all of the features of dependent claims 2-11, 13-15, and 17-22 for at least the above-cited reasons. Accordingly, Applicants respectfully submit that dependent claims 2-11, 13-15, and 17-22 are patentable over Shen, and request withdrawal of the 35 U.S.C. § 103(a) rejection thereof.

**Rejections under 35 U.S.C. § 103 over Shen**

Claims 23-25 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Shen.

**Independent Claim 23**

Independent claim 23, as currently amended, recites features similar to those described above for amended independent claims 1 and 12 such as clinically related data including multidimensional extensions that reflect groupings and logical structures not present in the raw data elements and employing those multidimensional extensions in a comparative analysis. Thus, the remarks provided above for independent claims 1 and 12 apply equally to amended independent claim 23.

Independent claim 23 has also been amended to further recite that overrides of the altered selected guideline, policy, or procedure by users are catalogued. *See Applicant's Specification* at ¶ [0022]. Shen does not describe cataloging or tracking overrides to guidelines, policies, or procedures by users. Shen mentions measuring and tracking the degree of implementation of standards and guidelines for quality control. *See Shen* at ¶ [0022]. However, this is merely descriptive of tracking the use of the standards and guidelines and not overrides of the procedures set out by the standards and guidelines, as recited by amended independent claim 23.

For at least the above reasons, Applicants respectfully submit that Shen fails to teach or suggest all of the claim features of amended independent claim 23. Applicants submit that claim 23 is patentable over Shen. Applicants respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of amended independent claim 23. Amended independent claim 23 is

believed to be in condition for allowance and such favorable action is hereby respectfully requested.

Claims 24-25 depend directly from amended independent claim 23. Applicants thus respectfully submit that Shen fails to teach or suggest all of the features of dependent claims 24 and 25 for at least the above-cited reasons. Accordingly, Applicants respectfully submit that dependent claims 24 and 25 are patentable over Shen, and request withdrawal of the 35 U.S.C. § 103(a) rejection thereof.

**New Independent Claim 35**

Independent claim 35 is newly submitted for consideration. New independent claim 35 includes features similar to those described above for independent claims 1, 12, and 23. Accordingly, Applicants respectfully submit that new independent claim 35 is patentable over Rosenfeld and Shen. Applicants respectfully request allowance of new independent claim 35.



**CONCLUSION**

For at least the reasons stated above, claims 1-4, 6-15, 17-25, and 35 are in condition for allowance. Applicants respectfully request withdrawal of the pending rejections and allowance of the claims. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned – 816-559-2564 or areed@shb.com (such communication via email is herein expressly granted) – to resolve the same. It is believed that the required fees are submitted herewith, however, the Commissioner is hereby authorized to charge any additional amount required to Deposit Account No. 19-2112.

Respectfully submitted,

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